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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

OH, TAYLOR V

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 08/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/673,411

Applicant(s)

FESTO, NORBERTO

Examiner

Taylor Victor Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,9,13-15 and 18-38 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 1,3,4,9, 13-15, 18-28,31-32, and 34-35 is/are rejected.
- 7) ☒ Claim(s) 29,30,33 and 36 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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1. Applicant's arguments with respect to claims 1, 3, 4, 9, 13- 15 and 18-38 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

2. Claims 1, 4, 9, 13, 15, 18-19, 23,25-28, and 31-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 9, 13, 18-19, 23,25-28, and 31-32, terms such as either “one or more active ingredients” or “ the active ingredient” are written. However, both do not describe what the active ingredients are in the claims. An appropriate correction is required.

In claims 4 and 15, “ other compatible ingredients” are written. However, this does not describe what the other compatible ingredients are in the claims. An appropriate correction is required.

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Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1, 3, 4, 9, 13-15, 18-28, 31-32, 34-35, and 37-38 are rejected under 35

U.S.C. 103(a) as being unpatentable over Barz et al (EP 0390206) in view of Gross et al (U.S. 5,686,102).

Barz et al teaches stable emulsions containing perfluoropolyether from 0.01 to 99.9% by weight based on the total weight (see page 6, lines 14-30) with various molecular weights such as 870, 1320, and 6600 (see page 7, lines 24-25). Also, the applications for the emulsions are creams or pastes to prevent contact irritations and dermatitis or to protect the skin from sun (see page 6, lines 51-54).

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However, Barz et al differs from the instant invention in that perfluoropolyether is used in combination with phosphatidycholine between 0.1 % and 20 % by weight and anti-inflammatory drugs such as ibuprofen, piroxicam, and the transabsorption of drugs is increased to more than five times its normal value.

Furthermore, Gross et al teaches a pharmacological composition for topical administration involved in the use of perfluoropolyethers (see col. 3 , line 19), phosphatidycholine in the range of from 30 to 99% (see col. 2 , lines 40-41) , and dermatological active compounds containing antibiotics, anti-infectious agents, and anti-inflammatory drugs such as ibuprofen, piroxicam (see col. 4 , lines 1-11). In addition, Gross et al has indicated that topical administration is formulated in such a way that pharmacological active compounds are delivered into a deep layer of the skin by means of a transdermal transport (see col. 1 , lines 5-11).

Concerning phosphatidycholine between 0.1 % and 20 % by weight, Gross et al do teach that phosphatidycholine is employed in the range of from 30 to 99% (see col. 2 , lines 40-41). The claimed range and the prior art do not overlap, but they are close enough so that one skilled in the art would have obtained the claimed range by routine experimentations of the water concentration in the cleavage product.

With respect to the transabsorption of drugs increased to more than five times its normal value, the references are silent. However, Gross et al do teach that topical administration is formulated in such a way that pharmacological active compounds are delivered into a deep layer

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of the skin by means of a transdermal transport (see col. 1 , lines 5-11). Therefore, if the person having an ordinary skill in art had desired to improve the transdermal transport, it would have been obvious for the skillful artisan in the art to have obtained more than five times its normal value of by routine experimentations on the formulation of the pharmacological composition for topical administration.

Barz et al does teach the stable emulsions containing perfluoropolyether with various molecular weights applicable to creams or pastes to prevent contact irritations and dermatitis or to protect the skin from sun and Gross et al does teach the pharmacological composition containing perfluoropolyethers , phosphatidycholine , and dermatological active compounds containing antibiotics, anti-infectious agents, and anti-inflammatory drugs for topical administration involved in the deep tissue delivery by means of the transdermal transport. Both have been involved in the use of perfluoropolyether applicable to the topical administrations such as creams and pastes. Therefore, it would have been obvious for the skillful artisan in the art to have motivated to incorporate Gross et al's phosphatidycholine and dermatological active compounds into Barz et al's emulsions for the deep penetrating topical administration with an expectation of a similar success as in Gross et al's formulation because Gross et al expressly teaches the pharmacological composition applicable to the deep penetrating topical administration containing perfluoropolyethers , phosphatidycholine , and dermatological active compounds containing antibiotics, anti-infectious agents, and anti-inflammatory drugs.

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6. Claims 29-30, 33, and 36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. Victor Oh whose telephone number is (703) 305-0809. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman, can be reached on (703) 308-4698. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

rev
8/10/02

Alan L Rotman
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